

2024728-7034083001
BSC No. 02-061US2REMARKS

Claims 67 and 76 have been amended to more particularly point out what the Applicants regard as their invention. No new matter has been added. Claims 67-82 remain pending in this application.

Rejections Under 35 U.S.C. §102(e)

Claims 67-72, 74, 76-78, 80 and 81 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Burbank (6312429). Applicants respectfully traverse and request reconsideration and withdrawal of the rejection. Applicants note that in order to sustain a rejection under §102, each and every limitation of the claim must be expressly or inherently presented in the cited reference. (M.P.E.P. §706.02).

As amended, Claims 67 and 76 each recites among other things a probe for deploying electrode arrays, comprising a first connector coupled to a shaft for connecting a first electrode array to one pole of a power supply; and a second connector coupled to the shaft for connecting a second array to a second pole of a power supply, wherein the first electrode array and the second electrode array are electrically isolated from each other. Such a device is not disclosed in or suggested by Burbank.

While Burbank does show wire arrays that may be deployed in opposed directions and that may further be electrically energized, Burbank falls far short of teaching each and every claim limitation in amended claims 67 and 76. For example, Burbank describes only "monopolar" energization of the wire arrays. Indeed, the structure described in Burbank fails to electrically isolate the arrays so that the devices are incapable of bipolar operation. The latter point can be seen, for example, in Figures 3 and 4 where wires 50 are carried by metal shaft 54 and wires 42 are carried

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by metal shaft 31. The metal shafts slide in direct engagement and are therefore not isolated. Moreover, when the wires are deployed, they also appear to be in direct contact, as shown, for example in Figure 10.

While Burbank suggests that the device may be "bipolar" at col. 4, lines 25-28, the specific teaching is that "a return electrode (not shown)" may be placed somewhere on the device. There is no teaching or suggestion anywhere that the two wire electrode arrays may themselves be operated in a bipolar manner, *i.e.* acting as the opposite poles of a radiofrequency power circuit. Accordingly, Applicants respectfully submit that independent claims 67 and 76, as well as claims 68-72, 74, 77-78, 80 and 81, which depend from claims 67 and 76, are allowable over Burbank.

Rejections Under 35 U.S.C. §103(a)

Claims 73 and 79 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Burbank. Claims 75 and 82 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Burbank in view of Wampler (6165175), and further in view of Mahvi (2002/0022864). Without conceding that Mahvi is actually prior art, Applicants respectfully traverse and request reconsideration and withdrawal of the rejections.

As described above, Burbank does not disclose or suggest the combination of elements in claims 67 and 76. Accordingly, Applicants respectfully submit claims 73 and 79, which depend from claims 67 and 76, respectively, are also allowable over Burbank. The fact that the claimed invention may be within the capabilities of one of ordinary skill in the art is not sufficient to establish obviousness. M.P.E.P. §2143.01 (citing *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999) (The level of skill in the art cannot be relied upon to provide the suggestion to combine references.))

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As a preliminary matter, Applicants reserve the right to submit evidentiary affidavits or declarations under 37 C.F.R. §1.131 to antedate the Mahvi publication for purposes of removing it as prior art under §103/102(e)(1). In the meantime, Applicants respectfully submit that the question of whether Mahvi is properly prior art as to the present application is moot, since it does not provide a proper basis for sustaining the present claim rejections.

In order to establish a case of obviousness under 35 U.S.C. §103 by combining references, there must be some suggestion or motivation provided either in the references themselves or in the generally available knowledge to combine the reference teachings, as well as some reasonable expectation of success in so doing. (M.P.E.P. §706.02(j)). According to the Office Action:

[I]t would have been obvious to one having ordinary skill in the art at the time the invention was made to make the electrode arrays of Burbank bipolar based on the Wampler et al. teaching that it is advantageous to use a bipolar device when cutting tissue as is the case with the electrode arrays of Burbank, to ensure that the flow of current is confined to the tissue in the instrument and to a significantly lesser extent to the tissue adjacent the instrument. It would have also been obvious based on the Mahvi teaching that the structural bipolar connection of electrode arrays are old and well known in the art.

Applicants respectfully disagree. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. §2143.01 (citing *In re Mills*, 916 F.2d 680, 682, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990) (Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so.")) The fact that the claimed invention may be within the capabilities of one of ordinary skill in the art is not sufficient to establish obviousness. M.P.E.P. §2143.01 (citing *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999) (The level of skill in the art cannot be relied upon to provide the suggestion to combine references.))

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The Burbank device deploys a plurality of locator wires 42 and 50 attached to a trocar 22 into tissue "to anchor the trocar 22 in place, and to identify the tissue to be removed in subsequent surgery." (Col. 11, line 65 to col. 12, line 6, emphasis added). "When the surgeon [later] opens the tissue region, the trocar and the deployed locator wires 42, 50 provide the surgeon direct indication of the area of tissue to be removed or otherwise operated upon." (Col. 12, lines 22-25). This biopsy is "to determine whether or not [the removed mass] is malignant." (Col. 1, lines 29-30).

The tips of the locator wires may be electrically energized to facilitate their deployment "electrosurgically" by cutting tissue directly adjacent to the wires, but the wires 42 and 50 are *not* used to perform an ablation procedure by cutting tissue between the wires.

Thus, the "electrosurgical lesion location device" disclosed and described in Burbank is used to isolate and mark tissue that is to be subsequently removed surgically and analyzed histopathologically to search for signs of malignancy. It is not a device used to ablate the tissue. Rather, the electrosurgical aspects of Burbank are employed for the purpose of facilitating movement of the trocar tip 30, and locator wires 42 and 50, through tissue and into position, before the handle 24 is removed and the patient operated on.

Incorporating Wampler's bi-polar electrosurgery device or Mahvi's ablation electrode into Burbank's respective pluralities of locator wires would result in a thermal ablation of the tissue between the locator wires instead of cutting the tissue directly in front of the locator wires. This ablation would destroy the tissue between the locator wires and affect the ability of those wires to anchor the trocar. Also, the destroyed tissue would be unavailable for histopathological examination, which may lead to a failure to diagnose a malignancy. As such, the proposed modification of Burbank in light of Wampler or Mahvi renders Burbank, unusable for its intended purpose, i.e. securing a trocar and biopsying tissue for histopathological examination. Consequently,

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there is no suggestion or motivation in Wampler or Mahvi to make the proposed modification to Burbank. M.P.E.P. §2143.01 (citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1 ¶25 (Fed. Cir. 1984)).

Modifying the locator wires disclosed in Burbank to include Wampler's bi-polar electrosurgery device or Mahvi's ablation electrode is equivalent to turning the liquid strainer in *In re Gordon* upside down, because ablating the tissue between the locator wires would both render that tissue unavailable for histopathological analysis and reduce the anchoring ability of the locator wires. Modifying the locator wires disclosed in Burbank to include Wampler's bi-polar electrosurgery device or Mahvi's ablation electrode is not like the modification in *In re Dance*, because ablation of tissue between the locator wires is not merely an added function, but instead renders Burbank's locator wires unusable for their intended purpose. M.P.E.P. §2143.01 (citing *In re Dance*, 160 F.3d 1339, 1344, 48 USPQ2d 1635, 1638 (Fed. Cir. 1998)).

For the foregoing reasons, Applicants respectfully submit that there is no suggestion or motivation to modify Burbank in light of either Wampler or Mahvi, except using hindsight based on Applicants' disclosure, which is not a proper motivation to combine references. As such, Applicants respectfully request that the rejections of claims 73, 75, 79 and 82 under §103(a) be withdrawn.

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CONCLUSION

Based on the foregoing, the claims are believed in condition for allowance. If the Examiner has any questions or comments regarding this response, the Examiner is respectfully requested to contact the undersigned at the number listed below.

Respectfully submitted,
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